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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,617	10/15/2001	Peter C. Ruenitz	235.0006 0102	6396

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EXAMINER

MAIER, LEIGH C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/981,617

Applicant(s)
Ruenltz

Examiner
Leigh Maier

Art Unit
1623



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1535 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-39 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27, 28, 30-37, and 39 is/are rejected.
- 7) ☒ Claim(s) 29 and 38 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2, 4 6) ☐ Other: _____

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DETAILED ACTION

Status of the Claims

By pre-amendment, claims 1-26 have been canceled. New claims 27-39 have been added and are pending.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 37, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by RUENITZ et al (J. Med. Chem., 1996).

RUENITZ et al discloses a compound of the structural formula recited in the claims. See compound 9 in scheme 1. The reference does not explicitly describe a pharmaceutical composition comprising this compound. However, the compound is tested in two *in vitro* systems which act to model a physiological system. See Tables 1 and 2 at page 4855 and page 4858, right-hand column, first full three paragraphs. Therefore these tests inherently comprise the compound in a pharmaceutically acceptable carrier.

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Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 28, and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over RUENITZ et al (J. Med. Chem., 1996) as applied to claims 36, 37, and 39 above, and further in view of RUENITZ (US 5,189,212).

The invention is drawn to the treatment for treating extra-reproductive tissues that are responsive to estrogen comprising administering to a patient an effective amount of a compound of the structural formula recited in the claims. It is noted that the claim does not recite the treatment of specific symptoms or disorders associated with estrogen deficiency or the administration to a population in need of treatment. The claim requires only the administration of the compound such that it would come into contact with the recited extra-reproductive tissues. It is further noted that osteopenia is a generic term for disorders comprising bone loss, such as osteoporosis.

RUENITZ et al teaches as set forth above. The reference further discloses that compound 9 is a full estrogen with potency approaching compound 8, an unsaturated triarylethylene compound similar in structure. See page 4855, right-hand column, third full paragraph.

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RUENITZ '212 teaches a genus of estrogenic triarylethylene compounds that have utility as a nonsteroidal hormone replacement and in treating disorders responsive to estrogen, such as osteoporosis. See abstract and col 4, lines 6-15. Note that this genus of compounds comprises 4-HTA, which is also compound 8, disclosed by RUENITZ et al and discussed above. See Figure 1 of RUENITZ '212 and compare with Scheme 1 of RUENITZ et al.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer estrogenic compound 9 to a peri/post-menopausal female for hormone replacement therapy or to treat disorders responsive to estrogen, such as osteoporosis. One of ordinary skill would reasonably expect success as RUENITZ et al had taught that the compound is a pure estrogen and RUENITZ '212 had taught that similar estrogenic compounds have utility for these purposes. It would be further obvious and within the scope of the artisan to prepare pharmaceutical compositions to be used for this purpose.

Allowable Subject Matter

Claims 29 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The art of record does not teach or fairly suggest a pharmaceutical composition comprising a compound having the R₁ moiety not containing an oxygen atom directly attached to the phenyl ring as recited in the claims or its use in a therapeutic method.

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Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, or Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier
Patent Examiner
October 31, 2002